United States Court of Appeals

for the Second Circuit

APPELLANT'S BRIEF

ORIGINAL WITH PROOF OF SERVICE

75-7122

UNITED STATES COURT OF APPEALS

for the

SECOND CIRCUIT

DANIEL FRIEDLANDER, ISADORE JACOBS, HARRY RONIS, and STANLEY WEINREB on behalf of themselves, and all other persons similarly situated,

Appellants,

v.

JOSEPH CIMINO, M.D., individually and as Commissioner of the Department of Health of the City of New York; the Department of Health of the City of New York; the Board of Health of the City of New York; GORDON CHASE, individually and as Administrator of the Health Services Administration, and the Health Services Administration; HOLLIS S. INGRAHAM, M.D., individually and as Commissioner of the Department of Health of the State of New York and the Department of Health of the State of New York; the Public Health Council of the Department of Health of the State of New York; CASPER WEINBERGER, individually and as Secretary of the Department of Health, Education, and Welfare of the United States of America and the Department of Health, Education, and Welfare of the United States of America,

Appellees.

ON APPEAL FROM AN ORDER OF THE UNITED STATES DISTRICT COURT FOR THE SOUTHERN DISTRICT OF NEW YORK

APPELLANTS' BRIEF

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Appellees.

APPELLANTS' BRIEF

PRELIMINARY STATEMENT

This class action was commenced by the filing of a complaint and the issuance of a summons on May 22, 1973.

The four named plaintiffs are non-physician clinical laboratory directors in the State of New York (two of them, Friedlander and Ronis, are directors of laboratories in the City of New York) and bring this class action on behalf of all other non-physician clinical laboratory directors in the State of New York.

Briefly, appellants' complaint alleges that appellees require them to perform certain tests of their professional proficiency on specimens, prepared by appellees, which are faulty, ill-prepared, and incapable of accurate testing. The complaint also alleges that appellee enforce their regulations in a discriminatory manner, to the detriment of plaintiffs. Finally, plaintiffs allege that the regulation scheme of their profession unconstitutionally discriminates against their class. Defendants actions violate the plaintiffs' Constitutional rights to due process and equal protection of law.

Appellants seek the following relief:

1. Injunction barring appellees from requiring plaintiffs to perform proficiency testing.

2. Judgement requiring appellees to provide for the safety and welfare of all of the citizens of New York by not exempting any individual or group operating

a laboratory from the requirements of the Public Health Law, the New York City Health Code and other relevant regulations.

3. Judgment declaring the 42 U.S.C. 1395(s)x (10) (11), Conditions for Coverage of Services of Independent Laboratories, 20 CFR Cpt. 3, Pt. 405, and Section 405.1301 (b) void and unconstitutional and enjoining the defendant the Department of Health, Education and Welfare from economically coercing the plaintiffs by continuing to require the abusive performance testing either directly or indirectly.

4. Damages in the amount of $1,000,000.00 against each defendant, State, City and Federal, which is the fair value for the plaintiffs' and others similarly situated labor, materials and use of plaintiffs' equipment in testing the ill-prepared specimens submitted by the defendant Health Departments under threat of license revocation.

QUESTION PRESENTED

DOES APPELLANTS' COMPLAINT RAISE A SUBSTANTIAL FEDERAL QUESTION SUFFICIENT TO SUSTAIN FEDERAL JURISDICTION?

STATEMENT OF FACTS

The four named plaintiffs are non-physician, self-employed clinical laboratory directors in the State of New York. They bring this class action on behalf of themselves and all other non-physician, self-employed clinical laboratory directors in the City and State of New York against the Commissioner of the Department of Health of the City of New York, the Board of Health of the City of New York, the Administrator of the Health Services Administration and the Health Services Administration of the City of New York; the Commissioner of the State Department of Health and the Department of Health of the State of New York, the Public Health Council of the State Department of Health, the Secretary of the Department of Health, Education and Welfare of the United States and the United States Department of Health, Education and Welfare.

Plaintiffs allege that their rights under the due process and equal protection clauses of the Fourteenth Amendment have been violated by the state and municipal defendants.

Title V of the New York Public Health Law and Article 13 of the New York City Health Code provide in pertinent part that each clinical laboratory and its director must obtain permits authorizing the tests it may perform. To retain its permit, each clinical laboratory must participate in a proficiency testing program under which it is required to analyze chemical specimens sent by the State or City and then to report the results. The results are graded by the appropriate governmental agencies. A laboratory which repeatedly fails to perform sufficiently accurate tests will lose its permit.

The specimens provided are phony, faulty, and ill-prepared, and result in the appellants expending more time and energy than would be necessary were the specimens properly prepared. (A60)*

The New York Health Code provides that a specimen received by a laboratory shall not be tested or reported on if its apparent condition indicates that it is unsuitable for testing. Likewise a specimen which has become contaminated through handling or unsuitable because of a lapse of time shall not be tested. (N.Y.C. Health Code §13.25(f,g))

Defendants allege in the affidavit of Sylvia Blatt that this statute section permits laboratories

*A refers to pages in appendix.

to discontinue tests on unsuitable specimens provided for performance testing. The Court below stated this principle, citing the New York City Health Code §13.25.

Actually neither that section nor any other in the Health Code provides specifically for the discontinuance of tests for any reason on specimens provided for proficiency testing. The statute section cited applies to specimens received by a laboratory in the general course of its business. The cited sections were added as part of remedial regulations designed to combat the evils of laboratories which solicited specimens to be sent via the mail in this state and across the country as well. Those laboratories solicited mail-order tests from physicians even though, in many cases, the particular tests involved have to be performed within an hour or even less of specimen-taking. (A63)

In any case this is plainly an ineffective remedy for appellants who must incur the expense and time necessary to make such a determination. Appellant's affidavit in opposition to appellees motion for summary judgement indicates that a faulty specimen can actually result in a far greater expenditure of time, money and materials than a good specimen. A responsible laboratory director must re-check his entire testing procedure

to determine the cause of any unorthodox test result. All possible causes, including equipment and materials must be evaluated before a determination can be made that the specimen is at fau[illegible]. (A61)

The specimens sent to the laboratory for testing do not even conform with the New York City Health Department's own requirements for specimens submitted to its Bureau of Laboratories. Form 900N, submitted by physicians for Rh and Blood Group tests to the Bureau of Laboratories states that Clotted Blood must be submitted for testing by the Bureau. Yet the blood submitted to the laboratories for "proficiency testing" is liquid, not clotted. (A61-62)

In addition, laboratories used by the Health Departments as control or "reference" labs frequently arrive at widely different test results, thus requiring voiding evaluation of the involved specimen groups. (A62)

Paragraph 8 of the affidavit of Sylvia Blatt in support of appellees' motion admits that the "Department of Health conducted an experiment" involving prothrombin time tests. The work for this experiment was thus supplied free to the Department of Health which conducted this experiment under the guise of and in the context of proficiency testing. The appellants should not be so forced to perform such free labor for the Department of Health. (A29)

Appellants allege in their complaint that the defendants enforce their rules and regulations in a discriminatory manner. Appellees knowingly permit physicians and groups of physicians to operate clinical laboratories in violation of the licensing and proficiency testing requirements of applicable law. (A7)

The City Department of Health permits licensed physicians to operate private clinical laboratories for the purpose of performing tests on referral from other physicians in violation of the licensing and performance testing requirements to which licensed laboratories are subjected. The individuals and groups operating unlicensed clinical laboratories are not subject to the onerous permit and certificate of qualification fees required of the appellants herein. (A7)

Appellants,in the affidavit of Rose Berman, specifically cite five physicians, 24 groups of physicians, and eight Human Resource Administration facilities, and three clinics, all operating illegal laboratories in the City of New York. These laboratories do not have required permits; nor do they pay permit fees or engage in proficiency testing. Rose Berman has personally informed the New York City Health Department of each of these violations, yet no action has even been undertaken to enforce the departments regulations. (A64-69).

Furthermore, Rose Berman's affidavit cites three facilities, outside the City of New York, operating unlicensed, untested, illegal laboratories. Ms. Berman states that she has informed the New York State Department of Health of these violations and no action has been taken to enforce the state regulation. (A69)

The facilities named are all operated under the aegis of physicians, or, in the case of the Human Resources Administration facilities, the City of New York. They are not subject to any exception to regulation granted by the relevant statutes (discussed below). The Appellees, in full knowledge of the illegal nature of their operation, intentionally take no action to enforce the applicable regulations. (A64-69).

The State statute exempts from the permit requirement and the proficiency testing program laboratories operated by a licensed physician, osteopath, dentist or podiatrist who performs or whose employees perform laboratory tests or procedures "solely as an adjunct to the treatment of his own patients." N.Y. Pub. Health Law §579 (McKinney 1971). The New York City Health Code exempts only licensed physicians and their employees who perform tests in connection with the treatment of their own patients. N.Y.C. Health Code §13.03(a).

These practitioners operate their laboratories without being subject to 'performance' testing or Health Department inspection although there is no basis for concluding that they will properly perform these tests, know anything about testing, or will maintain adequate laboratory facilities.

In 1972 the defendant New York State Health Department offered physicians in private practice an opportunity to become clinical laboratory directors. Over 200 physicians applied for permits and all were rejected as unqualified. Yet, under the current law and regulations, these physicians along with more than 34,000 other M.D.'s in this state can continue to perform tests for their own patients. (A70)

The Department of Health, Education and Welfare, a defendant below, but not an appellant here, is the Federal agency duly authorized by Congress to promulgate regulations authorizing medicare reimbursements to medicare eligible persons for monies paid for clinical laboratory tests.

Pursuant to its mandate the Department promulgated regulations entitled Conditions for Coverage for Services of Independent Laboratories, CFR Title 20, Chapter III, Part 405 (hereinafter referred to as Rules).

Title 42 U.S.C. § 1395 (x) exempts physicians performing tests, either themselves or through employees, in the physician's office from the requirements of (1) licensing by State or local authorities and (2) compliance with any other regulations promulgated by the Secretary of Health, Education and Welfare for the health and safety of individuals.

Section 405.1301(b) of the Rules exempts physicians performing laboratory tests under certain conditions from the necessity of complying with the Rules.

> Services furnished by out-of-hospital laboratories under the direction of a physician, such as a pathologist are considered to be subject to the conditions where the physician holds himself and the facilities of his office out to other physicians as being available primarily for the performance of diagnostic tests. A laboratory maintained by a physician for performing diagnostic tests primarily for his own patients would be exempt from the conditions, even though such laboratory does diagnostic tests on referral from other physicians.
>
> Diagnostic tests furnished by out-of-hospital physicians whose primary practice is directly attending patients and/or consultations, even though conducted partly through diagnostic procedures are considered physicians' services rather than clinical laboratory services. As such, the office in which these services are provided is exempt from the conditions.

Rules §405.1312 and section 13.07(a)(2) of the New York City Health Code delegates to private professional

and quasi-professional organizations the authority to certify individuals as qualified laboratory directors and eligible for medicare reimbursements.

The Rules require that appellants be licensed by and comply with the regulations of the New York State or City Health Department in order to qualify for medicare reimbursement.

This adoption by The Department of Health, Education and Welfare of State and Local regulations forces the appellants to participate in the abusive, wasteful and unconstitutional "proficiency" testing programs of the New York State and City Health Departments in order to qualify for medicare reimbursement.

The exemption given to physicians allows them to qualify for medicare reimbursement without being subjected to state or local licensing requirements, abusive "proficiency" testing programs or the other "Conditions for Coverage" as well as the onerous permit and certificate of qualification fees required of the appellants herein.

The exemption given to physicians by 42 U.S.C. 1395(x)(s)and CFR §405.1301(b) allows them to employ unqualified persons to perform laboratory tests, whereas the appellants hiring practices are subject to strict regulations appearing in Rules 405.1312, 405.1313, and 405.1315.

POINT I

APPELLANTS' COMPLAINT RAISES A SUBSTANTIAL FEDERAL QUESTION SUFFICIENT TO SUSTAIN FEDERAL JURISDICTION.

The decision of the lower court misinterprets the thrust of appellants constitutional claims. Appellants complain not that they are tested, but that they are tested in a faulty,arbitrary and abusive way, and that this faulty and abusive test program deprives them of substantial property. Further, appellants complain that they are irrationally discriminated against by both by appellees' regulatory program and their policy of enforcement.

42 U.S.C. § 1983 provides:

> "Every person who, under color of any statute, ordinance, regulation, custom, or usage, of any State or Territory, subjects or causes to be subjected, any citizen of the United States or other person within the jurisdiction thereof to the deprivation of any rights, privileges, or immunities secured by the Constitution and laws, shall be liable to the party injured in an action at law, suit in equity, or other proceeding for redress."

It is unquestioned here that the appellees are acting pursuant to statutes and ordinances of the State of New York. Further, appellants contend that they are

being deprived of a recognized and substantial right granted by the Constitution, namely, the equal protection of the laws. See Hagans v. Lavine, 415 U.S. 528, 39 L.Ed. 2d, 577 at 587.

28 U.S.C. § 1343 (3) confers jurisdiction upon federal courts to redress the deprivation under color of State law . . . . any right or privilege . . . . secured by the Constitution of the United States . . ."

Clearly the court below had jurisdiction of appellants presented a claim of "sufficient substance to support federal jurisdiction." Hagans v. Lavine, 39 L.Ed 2d at 587.

In Goosby v. Osser, 409 U.S. 512, 35 L.Ed 2d 36 (1973) the Supreme Court defined "substantiality" by reference to several older cases.

In those cases "constitutional insubstantiality" was equated with "essentially fictitious" or "wholly insubstantial," Bailey v. Patterson, 369 U.S. 31, at 33; "obviously frivolous," Hannis Distilling Co. v. Baltimore, 216 U.S. 285 at 288; and "obviously without merit" Ex parte Poresky 290 U.S. 30, at 32. The terms "obviously" and "wholly" are legally significant and a claim is to be deemed constitutionally insubstantial only if prior decisions render the claims frivolous, not merely doubtful or questionable. Goosby v. Osser, 409 U.S. 512, at 518.

> "A claim is insubstantial only if '"its unsoundness so clearly results from the previous decisions of this Court as to foreclose the subject and leave no room for the inference that the questions raised can be the subject of controversy."' Ex parte Paresly 290 U.S. 30, at 32 quoting from Hannis Distilling Co. v. Baltimore, 216 U.S. 283, at 288."

Goosby v. Osser, 409 U.S. 512 at 518.

In Hagans v. Lavine, supra, the Supreme Court noted that the substantiality doctrine of federal jurisdiction has been questioned, citing Bell v. Hood, 327 U.S. 678, and characterized as "more ancient than analytically sound," quoting Rosado v. Wyman, 397 U.S. 397 at 404. 39 L.Ed 2d at 588. The Hagans court found it unnecessary to re-evaluate the doctrine since the case presented a sufficient claim. Nevertheless, the Court's comment indicated that the doctrine should not be slavishly applied nor unnecessarily expanded.

Appellants complaint alleged that the appellees permit physicians to operate private laboratories without complying with the licensing and testing requirements. The affidavit of Rose Berman lists twenty-four (24) HIP (Health Insurance Plan) groups, several physicians, and medical groups who operate private laboratories without laboratory permits, without laboratory directors and without being subject to the proficiency

testing program. This large number of unlicensed private physician operated laboratories is, at the very least, indicative of a laissez-faire approach to enforcement of the state and city laws by the defendants when physicians are involved.

The affidavit of Rose Berman in opposition to the motion to dismiss indicated that the appellees have been specifically informed of alleged violations of their regulations and have totally failed to act to correct these abuses. This pattern of intentional non-enforcement is discriminatory and causes injury to the appellants.

The appellees cannot take refuge in a claim of "bureaucratic inefficiency" when facts establish that specific instances of law-breaking have been ignored. This pattern of non-enforcement certainly raises the inference that the discrimination is intentional and is designed to discourage the non-physician clinical laboratory directors from practicing a profession for which they are qualified.

The affidavit of Rose Berman also indicates that the specimens upon which these tests are to be made are often faulty and ill-prepared. Therefore, the test results are often inconclusive and result in no more than a waste of the appellants' time. The repeated submission of faulty and ill-prepared specimens to appellants

may be evidence of an intent to discourage non-physicians from continuing to operate clinical laboratories.

The appellees have created an unreasonable classification by giving preferential treatment to physicians operating laboratories in their own practices as well as physicians who violate the law with apparent impunity. Section 11.31 of the New York State Sanitory Code prescribes the qualifications of a laboratory director. This section indicates that an M.D. degree alone is not sufficient to qualify one as a laboratory director. The failure of over two hundred physicians to qualify for laboratory director permits support the conclusion that a physician, per se, is not qualified to operate a laboratory, and the preferential treatment afforded physician operated laboratories is unreasonable and arbitrary and contrary to the alleged purpose of the regulating statutes.

Discriminatory enforcement of a valid law is a denial of equal protection and due process guaranteed by the Constitution. Yick Wo v. Hopkins, 118 U.S. 356 (1886). "The unlawful administration by state officers of a state statute fair on its face, resulting in its unequal application to those who are entitled to be treated alike, is not a denial of equal protection unless there is shown to be present in it an element of intentional or purposeful discrimination." Snowden v. Hughes, 321 U.S. 1, 8, 64 S.Ct. 397, 401, 88 L.Ed. 497, 508 (1944).

The lower court held that appellants' claim of discriminatory enforcement was constitutionally insubstantial because appellants failed to allege that appellees had knowledge of the numerous violations of its regulations. That conclusion is rather astonishing in light of the language of the complaint.

In the relevant paragraphs the complaint states:

> "26. The State and City Departments of Health and their adjunct agencies permit groups of physicians to operate clinical laboratories in violation of the licensing and performance testing requirements of the applicable law.
>
> 27. The City Department of Health and its adjunct agencies permit licensed physicians to operate private clinical laboratories for the purpose of performing tests on referral from other physicians in violation of the licensing and performance testing requirements to which licensed laboratories are subjected."

Appellants alleged that appellees "permit" physicians to operate laboratories in violation of the law. Websters defines "permit": (1) to consent to expressly or formally; (2) to give leave. Thus the complaint very clearly alleges that the acts imputed to the appellees are knowingly done. Ms. Berman stated that she has

personally informed the appellees of the violations of their regulations and that no action has been undertaken to enforce the law.

In view of the very specific language of appellants' complaint and the allegations of the affidavit submitted to the court, the decision below that the complaint fails in its allegations is untenable.

"State laws and regulations must be rationally based and free from invidious discrimination." Dandridge v. Williams, 397 U.S. 471 at 487.

The regulations challenged here discriminate between appellants laboratories and those operated by physicians and other professionals solely to perform tests on their own patients. In evolving a "rational basis" for this classification the court below said that there is a greater possibility that an erroneous laboratory result will go undetected when the result is not obtained by an attending physician possessing knowledge of the patient's symptoms and history. Unfortunately, this decision is not based on facts before the court. Rose Berman's affidavit clearly demonstrates repeated failures by physicians to accept correct test results which do not conform to their own pre-conceptions regarding symptoms. More importantly, the lower court rationale fails to recognize

that tests performed in a physician's laboratory are not necessarily nor are they required to be performed by the physician himself. There are no regulations stipulating who shall perform the laboratory tests in a laboratory operated by a physician allegedly to perform tests solely on his own patients. The New York City Health Code §1303(a) specifically allows physicians to perform tests through "employees." There are no qualification requirements for these employees. As the affidavit submitted by appellants in opposition to appellees motion below indicates, laboratory tests are performed by totally unqualified persons employed by the physicians. A test result reported to the physician, by an employee, differs in no way from that performed by appellants who are qualified personnel subjected to rigorous performance testing.

In either case the physician must evaluate the reported result in light of his knowledge of the patient's symptoms and history. To re-iterate, the lack of any regulation requiring physicians to perform their own tests themselves completely undermines the logic of the lower court's "rational basis."

Appellants complaint very clearly sets forth a substantial federal question. The complaint alleges that the appellees purposefully avoid enforcing their

own regulations when physicians are involved. The affidavit of Rose Berman substantiates appellants claims that the appellees have knowledge of numerous violations of their regulations and have failed to act. Secondly, appellants allege that the regulations under which they are forced to operate discriminate unconstitutionally. Those statutes exempt physicians and other professionals who own laboratories, in which unqualified personnel can perform tests from the regulation to which the appellants are subjected. There can be no rational basis for allowing untrained and unqualified persons to perform laboratory tests merely because the laboratory is owned by a physician and the test is performed on a patient of the physician.

It is apparent that these questions are not insubstantial since the facts alleged, if true, quite clearly establish a purposeful and invidious discrimination which denies appellants the equal protection of law they are guaranteed by the Constitution.

No prior decision of any federal court allows invidious discrimination among members of a class. Nor does any decision authorize discrimination among different groups whose alleged classification is not rational. Appellants very plainly set forth sufficient allegations to raise both these issues before the court below.

Contrary to the decision of the District Court appellants' complaint did allege intentional discrimination in enforcement of appellees regulations. Likewise, no rational basis has been suggested to justify the classification system imposed by the statutes challenged here. The rationale suggested does not account for the facts involved e.g., that totally unqualified persons can perform tests for physicians so long as the physician owns the laboratory and the tests are performed on patients of the physician.

CONCLUSION

The decision of the lower court should be reversed.

DATED: New York, New York
March 18, 1975

Respectfully submitted,

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On The Brief

Received 2 copies of the within
Appellants Brief
this 21 day of March 1975.

Sign ____________________

For: Hon Louis J. Lefkowitz Esq(s).

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Louis J. Lefkowitz
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NEW YORK CITY OFFICE

Received 2 copies of the within
Appellants Brief
this 21 day of March, 1975.

Sign ____________________

For: W Bernard Richland Esq(s).

Att'ys for Appellee

MAR 1975

Paul J. Curran (RJ)
March 21, 1975
UNITED STATES ATTORNEY

Received 2 copies of the within
Appellants Brief
this 21 day of March, 1975.

Sign ____________________

For: Hon Paul Curran Esq(s).

Att'ys for Appellee

Two COPIES OF THE WITHIN PAPER HAVE THIS DAY BEEN RECEIVED AT THE OFFICE OF THE CORPORATION COUNSEL
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CORPORATION COUNSEL